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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/095,323	06/10/1998	MICHAEL D. LAUFER	ASTXNA00100	9521

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EXAMINER	
SHAY, DAVID M	
ART UNIT	**PAPER NUMBER**
3735	

DATE MAILED: 11/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/095,323	LAUFER, MICHAEL D.	
	Examiner	Art Unit	
	david shay	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37 and 48-50* is/are pending in the application.

4a) Of the above claim(s) *1-27,48 and 49* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-37 and 50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 June 1999* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 9/5/98; 2/18/99
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

In view of the Order Returning Undocketed Appeal To Examiner issued on September 2, 2005, PROSECUTION IS HEREBY REOPENED. A non-final rejection is set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

The drawings are objected to because there are stray marks on Figures 9 and 10. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an

application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 28-37 and 50 are rejected under 35 USC 103 a, as being unpatentable over Clarke in combination with Waksman et al and the admitted prior art that the media is highly absorbant. Clark teaches a method of killing smooth muscle cells (see column 2, lines 16 to 50). Using ultraviolet radiation in the 240 two 280 nm range (see the paragraph bridging columns 2 and 3, for example) Waksman et al teach the well-known equivalence that treatments for blood vessels to prevent excess proliferation of smooth muscle cells (the paragraph bridging pages 3 and 4) is also useful on trachea and bronchi see page 5, lines 25 to 31). Thus it would have been obvious to the artisan of ordinary skill to employ the method in bronchial tissue, since these are equivalents, and are composed of smooth muscle cells that respond to the same irradiated treatments as blood vessels, as taught by Waksman et al and to employ a radioactive source, since this is a notorious equivalent to electromagnetic radiation for killing smooth muscle cells, as both electromagnetic radiation and radioactivity involve bombardment of the cells with highly energetic particles which are absorbed by the cells to disrupt their function and kill them, official notice of which is hereby taken and to use other wavelengths since the media is highly absorbent;

to employ the method on long lesions, which would require movement while radiating since lesions which cover long portions must be treated as well; and to employ the method in asthmatic lung, since there is no indication that the smooth muscle cells therein would respond any differently than those in nonasthmatic lung, thus producing a method such as claimed.

Applicant argues that the examiner's characterization of Waksman et al is conclusory and incorrect. The examiner must respectfully disagree Waksman et al clearly teaches that the use of radioactive irradiation can be used for the same purpose as light therapies Waksman et al specifically cites" prior attempts to inhibit restenosis of coronary arteries have included, among other things. The use of various light therapies, chemotherapeutic agents stents are correct me devices hot and cold lasers as well as the exposure of the stenotic site to radiation." Thus clearly. Waksman et al regards, all these various treatments as equivalents as they're all recognize treatments in the art for this condition.

Applicant then argues that the "independent method claim requires that the walls of the airway the irradiated to cause debulking." The examiner must note, however, that nowhere in the originally filed specification does applicant discuss any dosage parameters for any type of radiation, electromagnetic or radioactive, that would be required to cause debulking further is respectfully noted that the proliferation reduction discussed by Clarke is achieved by killing the cells. See for example column 2 lines 47 250" in operation the ultraviolet radiation kills smooth cells at the site, thereby reducing the risk of restenosis." Clearly, once these cells are killed, they will be removed by normal bodily processes and as a result, the smooth muscle will be debulked by the removal of the these dead cells. Similarly, Waksman et al teaches the destruction of smooth muscle cells. By using radioactive radiation again, the cells which have been killed will

be removed, thereby causing debulking of the stenotic area.

Waksman et al also clearly discloses the use of his device on bronchial tissue. See for example page 5, lines 25 through 27. "Nonvascular areas, which the present invention is also useful include the brain ventricles, esophagus, trachea, bronchi..." this disclosure is explicit and unequivocal. Use of the method of Waksman et al on bronchial tissue will cause damage to the various cell types present in therein. Applicant has postulated no feasible way in which cell damage to, for example mucous gland cells, would be avoided if either of the radioactive radiation of Waksman et al or the ultraviolet radiation of Clark or applied to bronchial tissue.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Tuesday through Thursday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak, can be reached on Monday, Tuesday, Thursday, and Friday. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DAVID M. SHAY
PRIMARY EXAMINER
GROUP 330